

New genomic techniques

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EU prepares for proposal on new genomic techniques

Published initiatives: [Legislation for plants produced by certain new genomic techniques](#)

Update

The European Commission is developing a proposal to amend the existing EU GMO legislative framework for genetically modified organisms (GMOs) to reflect recent advances in biotechnology and new genomic techniques.

What is changing?

The European Commission is preparing new legislation on plants that are produced by certain new genomic techniques (NGTs). The proposal also covers food and feed derived from such plants. This initiative covers targeted mutagenesis (mutations induced in target locations of the genome without insertion of genetic material) and cisgenesis (genetic material inserted into a recipient organism from a sexually compatible natural donor organism, e.g. gene from a wild potato into a domesticated potato) (Inception Impact Assessment, [European Commission 2021a](#)). Other NGTs are not within the scope of this initiative.

In its 2022 [public consultation](#), the Commission raised the following key issues to be addressed in its proposal.

KEY ISSUES

Adequacy of existing legal framework

Four out of five respondents to the consultation suggested that the existing provisions of the GMO legislation are not adequate for plants obtained by targeted mutagenesis or cisgenesis. 61% of the 1329 respondents believed that legislating targeted mutagenesis and cisgenesis under current GMO rules would have detrimental effects, such as limiting tools available to farmers to fight climate change and reduce pesticide use. Around 20%, in particular the organic farming sector, considered the status quo should be maintained because it depends on the current strict traceability and labelling provisions of the GMO legislation.

Risk assessment

61% of respondents were in favour of a different risk assessment approach to NGTs than provided in the current GMO framework. 34% favoured requirements adapted to the characteristics and risks of the specific plant, and 27% argued that risk assessment should not be required where plants could have been produced through conventional plant breeding. 22% believed that the current GMO risk assessment framework should be applied to NGTs.

Sustainability

51% of respondents were in favour of new rules including specific provisions for sustainability, while 41% considered there was no need for such provisions. Respondents identified benefits of NGTs including better use of natural resources, development of plant tolerance/resistance to biotic stresses such as plant diseases and abiotic stresses such as climate change, and improvements in yield.

Traceability and information provision

In response to the question of how best to trace plants produced by targeted mutagenesis and cisgenesis, 32% of respondents suggested public databases and registries. 27% supported documentation transmitted through the supply chain, and 19% favoured digital solutions such as blockchain.

30% of respondents considered that a product should not be allowed on the market if reliable analytical methods cannot be provided. This view was held by the majority of consumer and environmental organisations, NGOs, trade unions and citizens. As current analytical methods cannot differentiate products produced by NGTs, 63% called for analytical requirements to be adapted. Almost half of the business associations and most academic/research institutions considered that no analytical method should be requested.

Regarding consumer information, 29% of respondents believed that transparency can be achieved via a physical label on the final product (29%); 22% believed labelling was not necessary for those plants comparable to conventional plants. 22% considered that public databases are a sufficient source of information, and 18% proposed digital labels as a solution.

OTHER ISSUES RAISED BY RESPONDENTS

Coexistence with other types of agriculture

Maintaining seed purity and preventing contamination is a major concern of the organic sector, with some feeling that the development of NGTs is a risk to the sector. A related concern is who pays for contamination and economic loss.

Access to plant genetic resources

Should the new rules facilitate wider access to technologies/plant genetic resources?

SMEs

How can the rules facilitate the uptake of these technologies by SMEs to allow them to remain competitive? What sort of support is required?

Why?

In recent years, NGTs have advanced considerably around the world. In 2018 the European Court of Justice (ECJ) ruled that targeted mutagenesis associated with NGTs falls within the scope of the existing EU GMO legislation (Directive [2001/18](#); Regulations [1829/2003](#) and [1830/2003](#)), and therefore requires authorisation ([InfoCuria 2018](#)).

In 2021 the European Council requested the Commission to review the existing legislation in light of the ECJ ruling. Although this judgement only considered mutagenesis, not other emerging NGTs, the [European Commission \(2021b\)](#) considers that other techniques, such as cisgenesis, intragenesis and epigenome editing, are also subject to the requirements of the GMO legislation.

This study also noted that:

- some plant products obtained from NGTs could potentially contribute to the sustainability and biodiversity objectives (e.g. plants more resistant to diseases or climate change effects)
- existing GMO legislation is not appropriate for plants from NGTs and could discourage research within the EU
- the capacity to identify and measure the presence of GMOs through reliable detection methods is central to current rules, but plants from NGTs are indistinguishable from conventional plants, creating a problem for enforcement (ENGL 2019)
- there is significant concern among EU stakeholders about amending GMO rules in response to NGTs, with scepticism regarding their benefits, and fears about their safety and detrimental impact on organic farming.

European Commissioners and several Member States have voiced their support for a change of legislation ([Foote 2021](#), [2022](#)).

Timeline

The European Commission is expected to adopt a proposal by the second quarter of 2023.

What are the major implications for exporting countries?

The new proposal will be relevant to AGRINFO partner countries developing new genomic techniques, including Argentina, Brazil, Chile, China, Colombia, Costa Rica, Ethiopia, India, Kenya, Nigeria, Peru, the Philippines and Vietnam ([New Genomic Techniques dashboard](#)).

The current problems of detection and traceability in applying existing rules are likely to increase as uptake and commercialisation of NGT-produced plants advance. A revision of existing rules should bring greater clarity and certainty for exporters of both conventional and NGT-produced plants.

Background

There is no legal definition of “new genomic techniques”. The [European Commission \(2021b\)](#) defined NGTs as “techniques that are capable of altering the genetic material of an organism and that have emerged or have been mainly developed since 2001”.

Discussions around a potential new regulatory framework centre on the distinction between “conventional” genetic engineering and “new” genomic techniques. In conventional genetic engineering, certain traits related to one organism can be transferred into a second organism by inserting entire genes into the genome of another organism. These genes are not targeted, but inserted randomly into the genome.

By contrast, new genomic techniques are targeted, removing, recombining or adding individual parts of the DNA (nucleotides) to obtain certain effects, similarly to natural mutations that occur in living cells.

The debate within Europe as to whether NGTs should be subject to the same legislation as established GMO techniques is considerable and polarised. [EFSA \(2021\)](#) concluded that the mutations induced by NGTs are comparable to those that occur in conventional plant breeding. Environmental groups and the organic sector have expressed concern that, although more targeted than conventional techniques, new genomic techniques may have unforeseen consequences ([Friends of the Earth Europe 2021](#); [IFOAM 2021](#)).

Resources

Online resources from the European Commission:

- [New techniques in biotechnology](#)
- [New Genomic Techniques dashboard](#)

EFSA (2021) [Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques](#). EFSA Journal, 19(4): e06314.

ENGL (2019) [Detection of food and feed plant products obtained by new mutagenesis techniques](#). European Network of GMO Laboratories.

European Commission (2021a) [Inception Impact Assessment: Legislation for plants produced by certain new genomic techniques](#) [download].

European Commission (2021b) [Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16](#).

Foote, N. (2021) [Timmermans: Gene editing 'clear part' of sustainability action in agrifood](#). EURACTIV, 1 December.

Foote, N. (2022) [EU agri ministers renew push on genetic techniques to bolster sector](#). EURACTIV, 19 September.

Friends of the Earth Europe (2021) [Generation unknown: Exposing the truth behind the new generation of GMOs](#).

IFOAM (2021) [Civil society, farmers and business organizations: Vice-President Timmermans, don't deregulate GM crops & animals](#).

InfoCuria (2018) [Case C-528/16](#): Judgment of the Court (Grand Chamber) of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt.

Sources

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